Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

1. (Currently amended) A method of preparing a lyophilized composition comprising:

   (a) mixing

      (i) polyoxyethylene (POE) and polyoxypropylene (POP) blockcopolymer;

      (ii) a polynucleotide;

      (iii) a cationic surfactant; and

      (iv) a compound selected from the group consisting of monosaccharides, disaccharides, oligosaccharides, sorbitol, hydrophilic polymers, proteins and mixtures thereof;

   at a temperature below the cloud point of said block copolymer to form a mixture; and

   (b) cold filtering the mixture; and

   (c) lyophilizing the mixture.

2. (Original) The method of claim 1, wherein said block copolymer is of the general formula: $HO(C_2H_4O)_x(C_3H_6O)_y(C_2H_4O)_xH$; wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C_3H_6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of the hydrophilic POE portion (C_2H_4O) is between approximately 1% and 50% by weight.

3. (Original) The method of claim 1, wherein said block copolymer is of the general formula: HO $(C_3H_6O)_y(C_2H_4O)_x(C_3H_6O)_yH$; wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C_3H_6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of the hydrophilic POE portion (C_2H_4O) is between approximately 1% and 50% by weight.

4. (Canceled)

5. (Original) The method of claim 1, wherein said mixing step (a) is performed at a temperature of about -2°C to about 8°C.

6. (Currently amended) The method of claim 1 [4], wherein said cold filtration step is performed at a temperature of about -2°C to about 8°C.

7. (Original) The method of claim 4, wherein said cold filtration step is performed using a filter with a pore size of about 0.01 microns to about 2 microns.

8. (Original) The method of claim 2, wherein said block copolymer is CRL-1005.

9. (Original) The method of claim 1, wherein the cationic surfactant is selected from the group consisting of benzalkonium chloride (BAK), benethonium chloride, cetrimide, cetylpyridinium chloride, acetyl triethylammonium chloride, (±)-N-(Benzyl)-N,N dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (Bn-DHxRIE), (±)-N-(2 Acetoxyethyl)-N,N-dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (DHxRIE-OAc), (±)-N-(2-Benzoyloxyethyl)-N,N-dimethyl-2,3-bis(hexyloxy)-1 propanaminium bromide (DHxRIE-OBz) and (±)-N-(3-Acetoxypropyl)-N,N dimethyl-2,3-bis(octyloxy)-1- propanaminium bromide (Pr-DOctRIE-OAc).

10. (Canceled)

11. (Currently amended) The method of claim 1 [~~10~~], wherein said compound ~~amorphous cryoprotectant~~ is sucrose.

12. (Canceled)

13. (Currently amended) The method of claim 1, wherein said mixture comprises about 1% to about 20% (w/v) of said compound ~~amorphous cryoprotectant or crystalline bulking agent~~.

14. (Original) The method of claim 11, wherein the final concentration of sucrose is about 10% (w/v).

15. (Original) The method of claim 1, wherein said mixture additionally comprises a pH stabilizing physiologic buffer.

16. (Original) The method of claim 15, wherein said physiologic buffer is selected from the group consisting of: saline, PBS, HEPES, MOPS, BIS-TRIS, sodium phosphate, potassium phosphate, dibasic sodium phosphate (Na_2HPO_4), monobasic sodium phosphate (NaH_2PO_4), monobasic sodium potassium phosphate ($NaKHPO_4$), magnesium phosphate ($Mg_3(PO_4)_2 \cdot 4H_2O$), or D(+)-α-sodium glycerophosphate ($HOCH_2CH(OH)CH_2OPO_3Na_2$).

17. (Original) The method of claim 16, wherein said physiologic buffer is sodium phosphate.

18. (Original) The method of claim 15, wherein the concentration of said physiologic buffer in the mixture is from about 5 mM to about 25 mM.

19. (Original) The method of claim 17, wherein said sodium phosphate is at a concentration of about 5 mM to about 25 mM.

20. (Original) The method of claim 1, wherein the final concentration of said cationic surfactant present in said mixture is from about 0.01 mM to about 5 mM.

21. (Original) The method of claim 1, wherein the final concentration of said block copolymer present in said mixture is from about 1mg/mL to about 50mg/mL.

22. (Original) The method of claim 1, wherein the final concentration of said polynucleotide molecules present in said mixture is from about 1ng/mL to about 10mg/mL.

23. (Original) A product produced by the process of claim 1.

24. (Original) A stable, mono-dispersed product produced by reconstituting the product of claim 23 with an aqueous solution.

25. (Original) A product produced by the process of claim 4.

26. (Original) A stable, mono-dispersed product produced by reconstituting the product of claim 25 with an aqueous solution.

27. (Original) A product produced by the process of claim 15.

28. (Original) A stable, mono-dispersed product produced by reconstituting the product of claim 27 with an aqueous solution.

29. (Previously presented) The method of claim 9, wherein said cationic surfactant is benethonium chloride.

30. (Previously presented) The method of claim 9, wherein said cationic surfactant is cetrimide.

31. (Previously presented) The method of claim 9, wherein said cationic surfactant is cetylpyridinium chloride.

32. (Previously presented) The method of claim 9, wherein the cationic surfactant is acetyl triethylammonium chloride.

33. (Previously presented) The method of claim 9, wherein said cationic surfactant is (±)-N-(Benzyl)-N,N dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (Bn-DHxRIE).

34. (Previously presented) The method of claim 9, wherein said cationic surfactant is (±)-N-(2 Acetoxyethyl)-N,N-dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (DHxRIE-OAc).

35. (Previously presented) The method of claim 9, wherein said cationic surfactant is (±)-N-(2-Benzoyloxyethyl)-N,N- dimethyl-2,3-bis(hexyloxy)-1 propanaminium bromide (DHxRIE-OBz).

36. (Previously presented) The method of claim 9, wherein said cationic surfactant is (±)-N-(3-Acetoxypropyl)-N,N dimethyl-2,3-bis(octyloxy)-1- propanaminium bromide (Pr-DOctRIE-OAc).

37. (Previously presented) The method of claim 1, wherein said compound is one or more monosaccharides.

38. (Previously presented) A product produced by the process of claim 37.

39. (Previously presented) A stable, mono-dispersed product produced by reconstituting the product of claim 38 with an aqueous solution.

40. (Previously presented) The method of claim 1, wherein said compound is one or more disaccharides.

41. (Previously presented) A product produced by the process of claim 40.

42. (Previously presented) A stable, mono-dispersed product produced by reconstituting the product of claim 41 with an aqueous solution.

43. (Previously presented) The method of claim 1, wherein said compound is one or more oligosaccharides.

44. (Previously presented) A product produced by the process of claim 43.

45. (Previously presented) A stable, mono-dispersed product produced by reconstituting the product of claim 44 with an aqueous solution.